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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,315	10/29/2001	Robert V. Farese JR.	UCAL-105CIP2	1732

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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 04/22/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,315

Applicant(s)

FARESE ET AL.

Examiner

Valarie Bertoglio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30 days MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5,8,10-13,15,16,20,21 and 23, drawn to a non-human animal characterized by having a transgene altering the naturally occurring, endogenous DGAT gene and a method of using said animal, classified in class 800;800, subclass 3;8.
- II. Claims 1-8,10-16,20,21 and 22, drawn to a non-human animal characterized by having a transgene altering the naturally occurring, endogenous DGAT gene and further comprising a transgene comprising an exogenous DGAT coding sequence and a method of using said animal, classified in class 800;800, subclass 3;8.
- III. Claims 1, 3-5, 8 and 9, drawn to non-human animal characterized by having an extra, transgene-encoded endogenous DGAT gene, classified in class 800, subclass 8.
- IV. Claims 15-19, drawn to an in vitro assay for screening candidate agents for modulatory activity of DGAT activity, classified in class 435, subclass 4.
- V. Claims 15-18 and 20-23, drawn to an in vivo assay for screening candidate agents for modulatory activity of DGAT activity using a non-transgenic animal, classified in class 424, subclass 9.2.
- VI. Claims 24-26, 28 and 29, drawn to an in vitro assay for screening candidate agents for modulatory activity of DGAT expression, classified in class 435, subclass 6.

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- VII. Claims 24,25 and 27-29, drawn to an in vivo assay for screening candidate agents for modulatory activity of DGAT expression, classified in class 424, subclass 9.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are patentably distinct because the products differ in material composition and use. The animal of each invention is genetically distinct, is generated using different transgenes and technical methods and considerations. The phenotype of each animal is different. The purpose and use for the animal of each invention is different. The burden required to search any of Inventions I-III together would be undue.

Each of Inventions I-III are patentably distinct from each of methods IV and VI. The methods of Invention IV and VI are performed in vitro and thus, the animals of Inventions I-III are not required for the methods. Inventions I-III are classified separately from the methods of Inventions IV and VI. The burden required to search any of Inventions I-III together with either Invention IV or VI would be undue.

Each of Inventions I-III and Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case materially different animals can each be in the methods of Invention V and VII. Furthermore, each of Inventions I-III can be used in materially different processes such as determining the effects of altering DGAT expression on gene expression and activity.

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The methods of Inventions IV or VI and each of Inventions V and VII are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Inventions IV and VI are in vitro methods while Inventions V and VII are in vivo methods requiring transgenic animals. The methods of Invention IV and VI and Inventions V and VII are classified separately and it would require undue burden to search either of Inventions IV or VI together with either of Inventions V or VII.

The methods of Inventions IV and VI are patentably distinct because the purpose of Invention IV is to identify modulators of DGAT activity while the purpose of the methods of Invention VI are to identify modulators of DGAT expression. The assay of Invention IV is an activity assay that differs in method steps from the expression assay of Invention VI.

The methods of Inventions V and VII are patentably distinct because the purpose of Invention V is to identify modulators of DGAT activity while the purpose of the methods of Invention VII are to identify modulators of DGAT expression. The assay of Invention V is an activity assay that differs in method steps from the expression assay of Invention VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the searches for the groups are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio
Patent Examiner


DEBORAH J. REYNOLDS
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